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TOWNSEND and TOWNSEND and CREW LLP

By: 03/06/07

PATENT
Attorney Docket No. 021993-000100US
Client Ref. No.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

COREY S. MAAS, M.D.
SHELDON S. KABAKER, M.D.

Application No.: 10/678,594

Filed: October 3, 2003

For: SOFT TISSUE SUSPENSION DEVICE

Confirmation No. 6160

Examiner: Tyson, Melanie Ruano

Technology Center/Art Unit: 3731

APPELLANTS' BRIEF UNDER 37 CFR §41.37

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Sir:

Further to the Notice of Appeal filed on January 12, 2007, for the above-referenced application, Appellants submit this Brief on Appeal.

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1. REAL PARTY IN INTEREST

The real parties of interest in this appeal are the inventors, Corey S. Maas, M.D. and Sheldon S. Kabaker, M.D.

2. RELATED APPEALS AND INTERFERENCES

There are no other prior or pending appeals, interferences or judicial proceedings known to the Appellants or to the Appellants' legal representative which may be related to, directly affect or be directly affected by, or have a bearing on the Board's decision in the present appeal.

3. STATUS OF CLAIMS

The application was filed with seven claims, none of which have been canceled or amended, and all of which are presently being appealed.

4. STATUS OF AMENDMENTS

The only amendment made in this application was the substitution of formal drawings for the informal drawings submitted when the application was filed. The formal drawings have been entered, and the claims remain in the form in which they were presented when the application was filed.

5. SUMMARY OF CLAIMED SUBJECT MATTER

This invention resides in a medical device for performing cosmetic surgery to correct midface ptosis, which is the downward migration of the malar fat pads in the face due to the effects of gravity over time. The procedure in which the device is used involves the deployment of a suspension suture to reverse the sagging of the fat pads, as described in a paper published in 2002 by Sasaki et al. The full citation of this paper is given below. This paper, which also discloses the components and materials used for performing the procedure, is referenced in the present application and cited as the primary reference in all of the rejections that are the reason for this appeal. The device of the present invention is an improvement over these components and materials. Where the paper describes threading the ends of two sutures, which are termed a tissue-release suture and a suspension suture in view of their respective functions in the procedure, through a single eye at the end of one Keith needle and tying them to the needle, and repeating the process with the opposite ends of the same sutures and another Keith needle, the device of the present invention is an integral device that includes two rigid, straight shafts that are integrally fused to the ends of the sutures. One end of each shaft is thus fused to two sutures. The fusing of two sutures to a single shaft at the same end is unique and avoids the need for the surgeon to thread the sutures through an eye and tie them in place, while it also avoids the presence of knots in the sutures and provides a smooth transition from the sutures to the shaft.

Concise explanation of the subject matter defined in each of the independent claims involved in the appeal. The sole independent claim involved in this appeal in claim 1. As claimed in claim 1, the device of the present invention is a combination of two sutures, one of which is a suspension suture and the other a tissue-release suture, two shafts, and an anchor graft, in which the two sutures are fused together to one end of each shaft and the anchor graft is attached to the suspension suture. The components recited in claim 1 are shown in FIG. 1 and described in the specification at page 5, lines 1-3. The suspension suture is identified as element 12, the release suture as element 13, the two shafts as elements 14 and 15, and the anchor graft as element 16. Further information as required by 37 CFR § 41.37(v) is as follows.

Claim 1: Reference to the specification by page and line number, and to the drawings by reference characters:

A surgical device for suspending soft tissue to correct midface ptosis, said device comprising:	page 3, lines 17-31	FIG. 1, element 11
first and second shafts, each shaft being rigid and straight and each having a distal end and a proximal end	page 5, lines 11-19	FIG. 1, elements 14 and 15
first and second sutures defined as a suspension suture and a tissue-release suture, respectively, each	page 5, lines 1-10, and lines 20-29	FIG. 1, elements 12 and 13 (the

suture having a first and second end, the first ends of both sutures fused to the proximal end of said first shaft and the second ends of both sutures fused to the proximal end of said second shaft, and		sutures), elements 18 and 19 (the distal ends), and elements 20 and 21 (the proximal ends)
an anchor graft attached to said suspension suture.	page 5 line 30, to page 6, line 9	FIG. 1, element 16

Claim 1: Means plus function clauses and supporting structure, material or acts: none.

Claim 2: Means plus function clauses and supporting structure, material or acts: none.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 3, and 6 are rejected under 35 U.S.C. § 103(a) as obvious over Sasaki et al. (*Plastic and Reconstructive Surgery*, Vol. 110, No. 2, pp. 635-654 (2002) in view of Greenstein (United States Patent No. 5,964,773). Claim 2 is rejected under 35 U.S.C. § 103(a) as obvious over Sasaki et al. in view of Greenstein and further in view of Cappucci (United States Patent No. 5,964,773). Claims 4 and 5 are rejected under 35 U.S.C. § 103(a) as obvious over Sasaki et al. in view of Greenstein and further in view of Bonutti (United States Patent No. 5,403,348). Claim 7 is rejected under 35 U.S.C. § 103(a) as obvious over Sasaki et al. in view of Greenstein and further in view of Yoon (United States Patent No. 5,849,019).

7. ARGUMENT

(a) Claims Argued as a Group: Claims 1-7. The combination of Sasaki et al. and Greenstein fails to render obvious the inventions of Appellants' claims 1, 3, and 6.

In his rejection of claims 1, 3, and 6, the Examiner has recognized that the Sazaki et al. paper fails to disclose the fusing of the ends of the sutures to the proximal ends of the shafts, and has cited the Greenstein patent for this fusing. The disclosure of Greenstein however does not meet the deficiencies of Sasaki et al. and does not place Appellants' invention as recited in claim 1, and hence in claims 3 and 6 as well, which depend from claim 1, within the possession of the person skilled in the art.

Two limitations of Appellants' claim 1 are lacking from the disclosures of both Sasaki et al. and Greenstein, and these references also fail to suggest these limitations. The first of these limitations is the fusion of two sutures to a single shaft rather than one suture to one shaft, and the second is the fusion of the two sutures to the *end* of each shaft.

Greenstein does indeed disclose a suturing device that includes a suture "swedged" to a shaft, but the procedure in which Greenstein uses the suturing device does not involve two sutures, and Greenstein offers no suggestion of using its "swedging" method for more than one suture per shaft. "Swedging" is a relatively simple operation when only one suture is involved, but swedging two sutures to a common shaft is more difficult to achieve and raises a significantly greater risk of an insecure connection since it involves joining three parts at a single juncture by simple compression rather than two. Accordingly, the disclosure of a swedged joinder between a single suture and a single needle does not render obvious a swedged joinder of two sutures to the same point on a single needle. Appellants are aware of no disclosure in the prior art literature and no product ever having been manufactured or sold in which two sutures are attached to the same end of one needle, whether by "swedging" or any other fusion technique other than by the primitive tying method illustrated by Sasaki et al. The Examiner's search corroborates this by producing only the Greenstein patent, where only a single suture is swedged to the shaft of a single needle. In view of this state of the art, Appellants submit that a device in which two sutures are fused to the end of a common shaft is not obvious.

A further distinction is that Appellants' claim 1 calls for the two sutures being fused to the proximal *end* of the shaft, whereas the "swedging" in Greenstein is at a point significantly removed from the end. This is shown in the Greenstein Figures, specifically Figures 6, 7, 8, and 9 which show the suture swedged at the side of the shaft rather than the end. It is also described in the specification at column 1, lines 63-65, and at column 3, lines 14-16.

Greenstein has a functional reason for swedging at the side of the shaft rather than the end, a reason that has no bearing on the present invention. The reason is that the end of each shaft must remain free to be inserted into a *blind hole 38* in each of the "wings 17" at the end of the device. This placement of the ends of the shafts in the blind holes is shown in Figures 3, 10, and 11, and is described in the specification at column 2, lines 3-6 and 63-65. Greenstein also emphasizes the fact that the suture is required to exit each shaft *at an angle* -- see column 3, lines 14-16 -- so that the suture can pass around the ends of the "wings" and over the distal end 14 of the device. The seating of the ends of the shafts in the blind holes by tightening the suture loop is the procedure that the construction is designed for. This could not be achieved if the sutures were swedged to the ends of the shafts rather than to their sides. The modification that one would have to make to achieve Appellants' invention would therefore defeat the purpose and function disclosed in Greenstein.

To reiterate, therefore, Appellants' invention differs from the disclosures of Sasaki et al. and Greenstein by claiming the limitations embodied in the expression "the first ends of both sutures fused to the proximal end of said first shaft and the second ends of both sutures fused to the proximal end of said second shaft," *i.e.*, the limitation that *two* sutures are fused to the end of a common shaft and the limitation that the fusion is *at the ends* of the shafts rather than at the sides. Neither reference discloses either of these limitations.

(b) Claim Argued Separately: Claim 2. The combination of Sasaki et al., Greenstein, and Cappucci fails to render obvious the invention of Appellants' claim 2.

The limitation introduced by claim 2 is that the first and second shafts each terminate in a blunt tip. The Examiner has recognized that neither Sasaki et al. nor Greenstein disclose a shaft with a blunt tip, and has therefore cited Capucci for this missing element. The Cappucci cannula is hollow, however, bearing no relation to the shafts recited in Appellants' claims. Also, no sutures are involved -- the cannula is designed to inject fluids into a patient -- and the blunt tip is functional only in combination with an outer sharp-ended "introducer needle" (42) that slides over the cannula. Nothing of this nature is recited in Appellants' claims, and there is no reason why one would consult a description of a hollow cannula for injecting fluids that slides inside an introducer needle for ideas on how to modify a shaft with sutures fused to one end, or in general for ideas on modifying equipment or procedures used in performing tissue suspension to correct midface ptosis. Even if one were to consider these three references in combination, there is nothing in any of the three references, without the benefit of hindsight, to indicate where in the Sasaki et al. disclosure or in the Greenstein disclosure the blunt tip would be placed.

For these reasons, Appellants submit that the invention of claim 2 is independently patentable and hereby request separate consideration of this claim.

(c) Claims Argued as a Group: Claims 4, 5, and 7. The combination of Sasaki et al. Greenstein, and Bonutti fails to render obvious the inventions of Appellants' claims 4 and 5, and the combination of Sasaki et al. Greenstein, and Yoon fails to render obvious the inventions of Appellants' claim 7.

Appellants do not request separate consideration of claims 4, 5, and 7, but instead rely on the distinctions presented above in part (a) of this section. Bonutti is cited for its disclosure of a suture anchor as in Appellants' claims 4 and 5, and Yoon is cited for its disclosure of a manually releasable clamp as in Appellants' claim 7. These claims are dependent claims depending from claim 1, and the distinctions enumerated above with respect to claim 1 apply.

8. CONCLUSION

For all of the reasons in the preceding section, Appellants respectfully submit that all claims on appeal recite patentable subject matter and request that the Honorable Board reverse all rejections.

Respectfully submitted,

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9. CLAIMS APPENDIX

Claim 1: A surgical device for suspending soft tissue to correct midface ptosis, said device comprising:

first and second shafts, each shaft being rigid and straight and each having a distal end and a proximal end,

first and second sutures defined as a suspension suture and a tissue-release suture, respectively, each suture having a first and second end, the first ends of both sutures fused to the proximal end of said first shaft and the second ends of both sutures fused to the proximal end of said second shaft, and

an anchor graft attached to said suspension suture.

Claim 2: The surgical device of claim **1** in which said first and second shafts each terminate in a blunt tip.

Claim 3: The surgical device of claim **1** in which said proximal end of said first shaft is swedged on to the first ends of both sutures and said proximal end of said second shaft is swedged on to the second ends of both sutures.

Claim 4: The surgical device of claim **1** in which said anchor graft is toroidal in shape.

Claim 5: The surgical device of claim **1** in which said anchor graft is a microporous fluorocarbon polymer and toroidal in shape.

Claim 6: The surgical device of claim **1** in which suspension suture is a monofilament suture, and said tissue-release suture is a braided suture.

Claim 7: The surgical device of claim **1** further comprising a manually releasable clamp to receive the first and second ends of one of said sutures.

10. EVIDENCE APPENDIX

None.

11. RELATED PROCEEDINGS APPENDIX

None.